REMARKS

This paper is responsive to the Office Action dated November 2, 2004, which is the second action on the merits of the application.

Claims 1-33 and 36-40 are pending in the application, and under examination. Upon entry of this paper, claim 1 is amended in a manner that does not introduce new matter into the disclosure.

Further consideration and allowance of the application is respectfully requested.

Interview Summary:

The undersigned wishes to express his gratitude to Examiner Louis D. Lieto and Examiner Ram Shulka for the courtesy of an interview held at the Patent Office on March 1, 2005. The enablement and double patenting rejections were discussed. This paper incorporates amendments and remarks based on what was discussed during the interview.

Rejections under 35 USC § 112:

Claim 1 and its dependents are rejected under § 112 ¶ 1 as being enabled for full-length telomerase, but not for fragments of telomerase. The Office Action states the following:

1. Without limitations defining the functions of such fragments and subsequences, one of skill in the art would not know how they could be used.
2. [I]t is unpredictable as to which fragments, if any, are useable.
3. [I]t is not routine in the art to screen large number of fragments where the expectation of obtaining any function is unpredictable.

Applicants respectfully disagree.

With respect to the first point, it is not true that the claims have no limitations defining functions. In fact, the claims require two activities: the nucleic acid sequence in the polynucleotide encodes a telomerase reverse transcriptase protein *having telomerase catalytic activity when complexed with a telomerase RNA*. In addition, the presence of the polynucleotide in the cell has the effect of *increasing proliferative capacity of the cell.*

This comports with Example 9 and Example 14 of the Revised Interim Written Description Guidelines (promulgated by the Office on March 7, 2000). Both of these examples show claims that read on fragments of the prototype protein *that have the same function as defined in the claim.*

According to the Guidelines, the claims in the present application contain all the elements that are required.

With respect to the second point, the Examiner is respectfully reminded that there is nothing in the patent law that requires the user to be able to predict *in advance* which fragments are useable. By way of example, to make an active fragment of hTRT, the user could express a polynucleotide in which SEQ. ID NO:1 had been trimmed at one or both ends. They could then test the expressed protein in any one of a number of assays exemplified in the specification (e.g., Example 7), or available in the art. In other words, identification of active fragments can be determined empirically, and without undue experimentation.

The Examiner will be familiar with *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), which is particularly instructive for what can be done within the bounds of routine experimentation in the field of biotechnology. In *Wands,* the patent application claimed monoclonal antibodies of a particular specificity and affinity. The PTO contended that only 2.8% of the hybridomas obtained were proven to fall within the claim, and thus the claim was not enabled. However, *the Court held that Wands was fully enabled,* because it was standard practice to screen negative hybridomas in order to find one that makes the desired antibody (8 USPQ2d at 1406-07).

Note the parallels with the situation in the present application. *It was not possible in Wands to predict* what monoclonal antibodies amongst all those cloned would have the desired activity. Identification of particular antibodies falling within the claimed invention was entirely an empirical determination. In fact, the user had to test not only whether each cloned antibody bound its intended target — they also had to do an affinity titration to determine whether each clone had the desired affinity constant. Based on the technology available in the art at the time the *Wands* patent was filed, the Court recognized that this could involve considerable labor. However, the Court determined that it could be done without becoming "undue experimentation". The decisive point was not the *amount* of labor that was required, but the fact that the experimentation required was *of a routine nature.*

In fact, the problem suggested in the Office Action with respect to the invention claimed here lends itself to a more systematic approach. Rather than make and test fragments in a random fashion (similar to the random process of making monoclonal antibodies), the user could simply start with full-length hTRT, and trim the molecule from either end through repetitive cycles until activity disappears. Any intermediate fragment would then be expected to also have functional activity, allowing the user to practice a wide range of the claimed invention. The specification provides additional guidance in its

extensive analysis of motif regions. Ultimately, the determination of what fragments are functional is an empirical determination, based on the functional activity required by the claims.

With respect to the third point, the Office Acton suggests that skilled scientists who express recombinant protein do not fragment the protein in order to identify functional fragments. In fact, functional mapping is a strategy often used in academics by scientists studying structure function relationships in complex molecules. Much more sophisticated techniques are available that go beyond just making fragments (e.g., Singh et al., "High-resolution functional mapping of a cloned gene by genetic footprinting," Proc Natl Acad Sci U S A. 1997 Feb 18;94(4):1304-9).

The reason that fragmentation analysis is not always done by commercial production labs is that there may be no reason to do so: if the full-length protein is functional, then a commercial embodiment can be made with the native protein. Making sub-fragments might then be considered an unnecessary step, meaning that there would be no commercial incentive to do so.

However, by seeking to limit applicants' coverage to just the full-length telomerase, the Office would *create* an incentive for competitors to avoid paying royalties for the applicants' invention. As already explained, making functional fragments does not require undue experimentation. If the Office gives the public a way of avoiding the patent simply by trimming a few amino acids off either end, then competitors will surely do so — much to the detriment of the owners of the invention claimed here. This would be a poor reward for the enormous financial and intellectual investment that was invested by applicants in making the original discovery of the hTRT gene.

Such a result would be inconsistent with the public policy objective of patent law, which is to stimulate *genuine inventive activity* by providing inventors with *adequate commercial protection* for their invention.

The suggestion of the Examiners to indicate that the reference DNA has the full length of SEQ. ID NO:1 has been incorporated into claim 1 by way of this Amendment. Fragments of functional telomerase also falling within the scope of the claims are enabled by the specification, for the reasons explained.

Withdrawal of this rejection is respectfully requested.

Double patenting

Applicants acknowledge with gratitude withdrawal of the double patenting rejections with respect to U.S. Patent 6,475,789.

The pending claims stand newly rejected for obviousness-type double patenting with respect to USSN 09/721,477, U.S. Patent No. 6,261,836, and U.S. Patent No. 6,337,200.

The 09/721,477 application is less advanced in prosecution than the present case. Whether or not the subject matter is overlapping, the question of double patenting will not arise when this application is otherwise in condition for allowance.

The rejection in view of U.S. Patent 6,261,836 is acknowledged. Applicants undertake to file a Terminal Disclaimer or otherwise address this issue once the Office indicates that the application is otherwise in condition for allowance.

Applicants respectfully disagree with the double patenting rejection with respect to U.S. Patent 6,337,200. The 6,337,200 patent claims hTRT variants that are patentably distinct over the present disclosure. The inventorship and ownership of the 6,337,200 patent are different from that of the present application. Indeed, if the 6,337,200 patent was invented by an entirely independent laboratory, then no double patenting rejection would be made. Surely it is unfair to the owners of the invention claimed here to be subject to the complications of a double patenting rejection simply because the 6,337,200 patent and the present application share a single coinventor.

Withdrawal of this rejection is respectfully requested.

Request for Interview

Applicants respectfully request that all outstanding rejections be reconsidered and withdrawn.

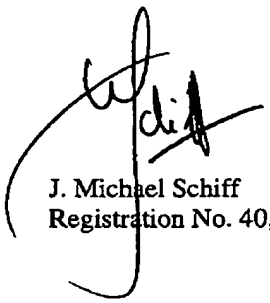
In the event that the Examiner determines that there are other matters to be addressed, the undersigned hereby requests a further interview by telephone.

Fees Due

Enclosed with this Amendment is authorization to charge the Deposit Account for the extension of time. No other fee is required with respect to the amendments to the claims, since the claim count has not changed.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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